All Phase II applications must include a succinct Commercialization Plan (formerly Product Development Plan [PDP]). Specific details for preparing this section are described in this solicitation.

SBIR and STTR Phase II awards normally may not exceed $750,000 total (direct costs, indirect costs, and profit/fee) for a period normally not to exceed 2 years (see "Recent Changes in STTR Legislation"). However, these award levels for time and amount are statutory guidelines, not ceilings. Therefore, you are encouraged to propose a reasonable budget and project period that is appropriate for completion of the research project. Deviations from the guidelines are acceptable, *but must be well justified. You are encouraged to discuss budgetary deviations with NIH program staff prior to submission of the application*.

Only Phase I grantees are eligible to obtain Phase II funding. This includes those awardees identified via a "successor-in-interest" or "novated" or similarly-revised funding agreement, or those that have reorganized with the same key staff, regardless of whether they have been assigned a different tax identification number. Agencies may require the original awardee to relinquish its rights and interests in an SBIR/STTR project in favor of another applicant as a condition for that applicant's eligibility to participate in the SBIR Program for that project.

You may submit a Phase II application either before or after expiration of the Phase I budget period, unless you elect to submit a Phase I and Phase II application concurrently under the Fast-Track procedure. *To maintain eligibility to seek Phase II support, a Phase I grantee organization should submit a Phase II application within the first six receipt dates following the expiration of the Phase I budget period*.

Only one Phase II award may be made for a single SBIR/STTR project.

Under special circumstances, requests for supplemental funds to existing NIH SBIR/STTR grants or requests for an extension of the period of support with funds may be considered. (*The awarding of supplemental funds applies to NIH ONLY, as CDC and FDA do not make awards greater than the stated guidelines*.)

PHASE III: Commercialization
No SBIR/STTR Funds

Phase III. An objective of the SBIR/STTR Program is to increase private sector commercialization of innovations derived from Federal R/R&D. During Phase III, the small business concern is to pursue commercialization with non-SBIR/STTR funds (either Federal or non-Federal). In some Federal agencies, Phase III may involve follow-on, non-SBIR/STTR funded R&D, or production contracts for products or processes intended for use by the U.S. Government.

The competition for SBIR/STTR Phase I and Phase II awards satisfies any competition requirement of the Armed Services Procurement Act, the Federal Property and Administrative Services Act, and the Competition in Contracting Act. Therefore, an agency that wishes to fund an SBIR/STTR Phase III project is not required to conduct another competition in order to satisfy those statutory provisions. As a result, in conducting actions relative to a Phase III SBIR/STTR award, it is sufficient to state for purposes of a Justification and Approval pursuant to FAR 6.302-5 that the project is a SBIR/STTR Phase III award that is derived from, extends, or logically concludes efforts performed under prior SBIR/STTR funding agreements and is authorized under 10 U.S.C. 2304(b)(2) or 41 U.S.C. 253(b)(2).

B. Fast-Track Applications

Fast-Track Applications: PHASE I + II
Parallel review option
Phase I and Phase II
submitted together
Commercialization Plan

The NIH Fast-Track mechanism expedites the decision and award of SBIR and STTR Phase II funding for scientifically meritorious applications that have a high potential for commercialization. Fast-Track incorporates a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together. The Phase I portion of a Fast-Track must specify clear, measurable goals (milestones) that should be achieved prior to initiating Phase II work. In addition, the Phase II portion of a Fast-Track application must present a Commercialization Plan (formerly Product Development Plan [PDP]) that addresses specific points. Instructions on the preparation of a Fast-Track application may be found in Section IV, E. Phase I/Phase II Fast-Track Review Option of this document.

prepared by a CPA engaged to conduct an annual audit should be submitted, if available. The F&A cost proposal should include a reconciliation with the income statement; that is, there should be a cross-referencing from amounts on the income statement to amounts shown in the proposal, and a clear identification of individual elements (labor, materials, other expenses, etc.) of independent (self-sponsored) research and development (IR&D) expenses. IR&D costs are not allowable under NIH awards.

2. Listing of categories of costs normally classified and claimed as direct costs on Federal awards and non-Federally supported projects or activities.
3. Explanation of how the organization accounts for paid absences (vacation, holiday, and sick leave).
4. Certification of Final Indirect Costs as specified in FAR Part 52.242-4. This Certificate is to be completed by an official at a level no lower than a vice president or chief financial officer of the business segment submitting the proposal.

Smoke-Free Workplace

Does your organization currently provide a smoke-free workplace and/or promote the nonuse of tobacco products or have plans to do so? Check the appropriate box marked "Yes" or "No." Response to the question has no impact on the review or funding of this application.

12. PERSONAL DATA

Use the "Personal Data Form Page" (MS Word | PDF). Follow the instructions on the form.

E. Phase I/Phase II Fast-Track

(*Applicable to NIH Only*.) Fast-Track is a review option designed to expedite the decision and award of Phase II funding for scientifically meritorious applications for projects that have a high potential for commercialization. Fast-Track involves the concurrent submission and peer review of both Phase I and Phase II applications. As such, Fast-Track offers the advantage of minimizing or eliminating the funding gap between Phase I and Phase II. Applications that do not meet the requirements listed below may be unscored or they may be redirected for review through the standard review procedures described above.

Before submitting a "Fast-Track" application, you are strongly encouraged to consult with the NIH program staff named in the table "Awarding Component Contact Information."

SBIR/STTR FAST-TRACK APPLICATION INSTRUCTIONS AND REQUIREMENTS

(***Reminder.*** Refer to the Fast-Track Reminder Sheet before submitting the application.)

1. Submit two complete applications - a complete Phase I and a complete Phase II application, including for each, the Face Page, Form Page 2 (Description/Abstract), Form Page 3 (Table of Contents), Budget Pages, Biographical Sketch Pages, Resources Page, Checklist Form Page, Introduction (revised applications only) and the Research Plan. Only one Personal Data Form Page is needed. Place this page as the last page of the Phase II application. Incomplete Fast-Track Applications may be significantly delayed in the review process.
2. Prepare the Fast-Track application in accordance with specific Phase I and Phase II grant application instructions and requirements. Refer to the "Specific SBIR/STTR Grant Application Instructions and Requirements" in this Solicitation and use the PHS 398 forms (http://grants.nih.gov/grants/funding/phs398/phs398.html).
3. Identify the application by typing the words "*Fast-Track: Phase I*" in Item 2 on the Face Page of the *Phase I application* and "*Fast-Track: Phase II*" in Item 2 on the Face Page of the *Phase II application*.
4. If you are submitting a *revised Fast-Track application*, include a one page Introduction in the Phase I (just before the Research Plan) and no more than 3 pages of Introduction in the Phase II application (just before the Research Plan).
5. Prepare the Research Plan in accordance with specified page limitations for items a-d in each Phase (15 pages for Phase I; 25 pages for Phase II).
6. Specify in the Phase I application clear, appropriate measurable goals (milestones) that should be achieved prior to initiating Phase II. The scientific peer review group will evaluate

the goals and may suggest other milestones that should be achieved prior to Phase II funding.

7. Submit a concise Commercialization Plan (formerly Product Development Plan [PDP]) as part of the Phase II application in accordance with the instructions above under Section IV., Research Plan, Item j, Commercialization Plan. The Commercialization Plan is limited to *15 pages*. Be succinct. There is no requirement for applicants to use the maximum allowable pages allotted to the Commercialization Plan.
8. Submit the completed Phase I and Phase II applications together in a *single* envelope or box.

Typically Fast-Track applications will receive a single rating. Failure to provide clear, measurable goals may be sufficient reason for the scientific review group to exclude the Phase II application from Fast-Track review. In this case, only the Phase I application will receive a score. Following the initial peer review, Fast-Track applications will receive secondary review by the advisory council or board of the NIH awarding component that is the potential funding component.

F. Market Research

The PHS will not support any market research under the SBIR/STTR programs. Neither will it support studies of the literature that will lead to a new or expanded statement of work. Literature searches where the commercial product is a database are acceptable.

For purposes of the SBIR/STTR programs, "market research" is the systematic gathering, editing, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the research project. It includes various types of research, such as the size of potential market and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a Research Plan or protocol that require a survey of the public as part of the objective of the project to determine the impact of the subject of the research on the behavior of individuals.

V. GRANT APPLICATION SUBMISSION REQUIREMENTS

The NIH's Center for Scientific Review (CSR) is the *single* receiving point for all NIH, CDC, and FDA SBIR/STTR grant applications. If your application is relevant to more than one awarding component, you need only submit the original application and five copies to CSR, and CSR will assign the application to all such components. Do not submit identical applications with requests for assignment to different funding components.

Cover Letters. You may include a cover letter with your application to:

- Suggest assignment(s) to potential awarding component(s) (e.g., NIA, NIAMS, NINDS).
- Indicate a specific area of expertise that should be represented on the study section committee.
- Identify competitors who have direct conflicts of interest.

A. Receipt, Review and Award Dates

A grant application submitted under this SBIR/STTR Phase I Grant Solicitation will be considered on time if it is received by or mailed on or before the published receipt date and a proof of mailing is provided.

Proof of timely mailing consists of one of the following: a legibly dated U.S. Postal Service postmark or a dated receipt from a commercial carrier or the U.S. Postal Service.

If the receipt date falls on a weekend, it will be extended to the following Monday. If the date falls on a holiday, it will be extended to the following workday. The application will be considered on time if it is received by or mailed on or before that day and a proof of mailing is provided.

The receipt date will be waived only in extenuating circumstances. To request a waiver, include an explanatory letter, addressed to the Division of Receipt and Referral, Center for Scientific Review, with the signed, completed application. No request for a waiver will be considered prior to receipt of the application.

2. Did the applicant submit a concise Commercialization Plan (formerly Product Development Plan [PDP]) that adequately addresses the specific areas described in Item j of the Phase II Research Plan?
3. Does the project carry a high degree of commercial potential, as described in the Commercialization Plan?

Amended Applications

In addition to the above criteria, the following criteria will be applied to revised applications.

1. Are the responses to comments from the previous SRG review adequate?
2. Are the improvements in the revised application appropriate?

PHASE I/PHASE II FAST-TRACK APPLICATION REVIEW CRITERIA

For Phase I/Phase II Fast-Track applications, the following criteria also will be applied:

1. Does the Phase I application specify clear, appropriate, measurable goals (milestones) that should be achieved prior to initiating Phase II?
2. Did the applicant submit a concise Commercialization Plan (formerly Product Development Plan [PDP]) that adequately addresses the specific areas described in Item j of the Phase II Research Plan?
3. To what extent was the applicant able to obtain letters of interest, additional funding commitments, and/or resources from the private sector or non-SBIR/STTR funding sources that would enhance the likelihood for commercialization?
4. Does the project carry a high degree of commercial potential, as described in the Commercialization Plan?

Phase I and Phase II Fast-Track applications that satisfy all of the review criteria will receive a single rating. Failure to provide clear, measurable goals may be sufficient reason for the scientific review group to exclude the Phase II application from Fast-Track review.

C. Release of Grant Application Information after Review

Following evaluation of your grant application by the SRG but prior to National Advisory Council or Board action, a summary statement will be sent automatically to the Principal Investigator. The identity of the reviewers will never be disclosed.

Applicants normally receive their summary statement within four to six weeks following the study section meeting in which it was reviewed. A "summary statement" documents the evaluation of an application by the SRG and conveys the SRG's recommendations to the awarding component and its Council or Board. The identity of the reviewers is never disclosed. No one other than the Principal Investigator (and appropriate NIH staff) may receive the summary statement and evaluation rating.

After the review meeting occurs, applicants are encouraged to address inquiries about review to their Program Director, rather than to review staff. After receipt/review of the summary statement, applicants are encouraged to contact their Program Director for guidance and advice.

Also following NIH peer review, applicant organizations will be notified of the need for review and certification for the proposed research by an OHRP- Registered Institutional Review Board (IRB). See http://ohrp.osophs.dhhs.gov to register an IRB. The certification of IRB approval from an official signing for the applicant organization must then be sent to and received by the Grants Management Office identified in the notice requesting IRB certification. This IRB certification must include: the PHS application number, title of the project, name of the Principal Investigator/Program Director, date of IRB approval, and appropriate signatures. You may also use optional Form 310, "Protection of Human Subjects" to provide IRB certification (see http://ohrp.osophs.dhhs.gov/humansubjects/assurance/OF310.rtf).

Any modifications in the Research Plan section of the application, required by the IRB, must be submitted with the follow-up certification. It is the responsibility of the Principal Investigator/Program Director and the applicant organization to submit the follow-up certification.

When a year will have elapsed between the initial IRB review date and the anticipated award date, awarding unit staff shall require re-review by the IRB and certification prior to award.

D. Funding Decisions

When making funding decisions, the awarding components take into consideration the following: (1) ratings resulting from the scientific and technical evaluation process; (2) areas of high program relevance; (3) program balance (that is, balance among areas of research); (4) available funds; and (5) the commercialization status where the small business concern has received more than 15 Phase II awards in the prior five (5) fiscal years, if applicable (see this application requirement under "Prior SBIR/STTR Phase II Awards" found in Section IV.D.9. Item Research Plan, Item k). The awarding component will notify the Principal Investigator and the applicant small business concern of the final disposition of the application.

Phase II applications will be selected for funding based on the project's scientific and technical merit, the awarding component's assessment of the Phase I progress report and determination that the Phase I goals were achieved, an update and verification of the Commercialization Plan (formerly Product Development Plan [PDP]) and any commitment(s) for funds and/or resources from an investor or partner organization, the project's potential for meeting the mission of the awarding component and potential for commercial success, and the availability of funds.

Fast-Track Phase II applications that are recommended for approval may be funded following submission of the Phase I progress report and other documents necessary for continuation.

E. Revision and Resubmission of Grant Applications

Grant applications that are not funded may be revised for resubmission on any of the published receipt dates (e.g., Apr 1, Aug 1, Dec 1). However, applicant organizations may submit no more than two revised applications within a period of two years from the receipt date of the initial, original application. The limit of two revisions allows applicant small business concerns and Principal Investigators sufficient time to consider the comments of the reviewers and address them. If an applicant is not successful after three attempts at funding (the initial submission and two revisions), she/he is expected to make a significant change in the direction and approach for subsequent applications. It is not appropriate to submit an essentially identical or only slightly changed application as a new application.

Resubmitted applications without substantive changes will not be accepted. All revised applications must include an Introduction. See Section IV.D., Item 9, for specific instructions. The revised application MUST address the issues identified in the previous summary statement for the previous submission that was not funded. *Revised sections must be clearly marked by appropriate bracketing, indenting, or changing of typography, unless the changes are so extensive as to include most of the text*. This exception should be explained in the Introduction. *Do not shade changes*. Upon acceptance of a revised application by the CSR, the prior version will be withdrawn from further consideration by the awarding components. Acceptance of the revised application will generally mean that it will fall into a later review and award cycle. *Resubmission of an application that merely duplicates a previous application is not acceptable and the duplicate application will be returned without review*.

F. Submission of Similar Grant Applications by the Applicant Organization to Other Federal Agencies

WARNING: While it is permissible with proposal notification to submit identical proposals or proposals containing a significant amount of essentially equivalent work for consideration under numerous Federal program solicitations, it is unlawful to enter into funding agreements requiring essentially equivalent effort. If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award.

Other support (not to be confused with Research Support requested on your Biographical Sketch) should only be submitted when requested by NIH. If you elect to submit identical applications or applications containing a significant amount of essentially equivalent work under other Federal program solicitations, you must include the following information as part of your "Other Support" information when requested by NIH:

- Name and address of the agencies to which applications were submitted or from which awards were received.